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Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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Majority (202) 225–2927
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January 16, 2020

Mr. Richard J. Hodes, M.D.
Director
National Institute on Aging
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Director Hodes:

We write to request information about the actions that the U.S. Department of Health and Human Services (HHS) has taken to cultivate innovation in Alzheimer's Disease and Alzheimer's Disease-Related Dementias (AD/ADRD or Alzheimer's) research, as well as barriers that stand in the way of discovering treatments or cures for AD/ADRD, and the ways in which Congress can assist in overcoming such barriers. Despite sustained federal involvement, Alzheimer's Disease remains the only top 10 cause of death in the United States that cannot be cured, treated, or slowed.[1]

Alzheimer's research and the search for a cure or treatment is, and has been, a priority of HHS for many years. Several HHS agencies, including the National Institute on Aging (NIA) of the National Institutes of Health (NIH), the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and the Centers for Disease Control and Prevention (CDC) are responsible for ensuring that various aspects of Alzheimer's research and prevention continue to progress.

The NIA was established in 1974, is one of the 27 Institutes and Centers of the NIH, and is the primary federal agency supporting and conducting Alzheimer's Disease research.[2] In 1984, the first Alzheimer's Disease Center was established, and the Drug Export Amendments Act of 1986 authorized "the NIA's Alzheimer's Disease Education and Referral (ADEAR) Center as part of a broad program to conduct research and distribute information about

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[1] Alzheimer's & Dementia 14 (2018) 367 – 439, Alzheimer's Association Report: 2018 Alzheimer's disease facts and figures at 383, *available at* https://www.alzheimersanddementia.com/article/S1552-5260(18)30041-4/pdf.
[2] National Institute on Aging, National Institutes of Health, *About NIA,* U.S. Department of Health and Human Services, *available at* https://www.nia.nih.gov/about.

Alzheimer's disease to health professionals, patients and their families, and the general public."[3] In 2003, NIA, along with the Alzheimer's Association, expanded "the Alzheimer's Disease Genetics Initiative to create a large bank of genetic materials and cell lines for study to speed up the discovery of risk-factor genes for late-onset Alzheimer's Disease."[4] In 2005, NIA's Alzheimer's Disease Preclinical Drug Development program was established, and in 2006, NIA led an NIH conference on Alzheimer's Disease to assess the current state of Alzheimer's Disease research and the most promising routes to progress.[5] As the largest grantor of Alzheimer's research funding and NIA's substantial involvement, we are interested in the progress NIA has made in Alzheimer's Disease research.

Congress has been active in promoting a cure or treatment for Alzheimer's, passing multiple pieces of legislation in the last decade. In 2011, Congress passed, and President Obama signed into law, the National Alzheimer's Project Act (NAPA). Through NAPA, Congress charged HHS with establishing the National Alzheimer's Project, which included six objectives regarding diagnosis, treatment, and research for AD/ADRD.[6] In pursuit of these six objectives, HHS promulgated the National Plan, which established five goals and acted as a road map for both the federal government and the research community.[7] In 2014, the Alzheimer's Accountability Act was enacted as part of the Fiscal Year (FY) 2015 omnibus appropriations bill.[8] The Alzheimer's Accountability Act requires the scientists at NIH to submit an annual Alzheimer's research budget proposal directly to Congress—known as the Alzheimer's Bypass Budget—specifying the resources that scientists need to reach the National Alzheimer's Plan goal of preventing and effectively treating AD/ADRD by 2025. In addition, in 2018, the Building Our Largest Dementia (BOLD) Infrastructure for Alzheimer's Act was signed into law.[9] In an effort to bolster AD/ADRD progress, the BOLD Act further authorized the expansion of activities related to combating AD/ADRD.

Congress has also demonstrated a commitment to AD/ADRD research by appropriating additional funding annually. For FY 2018, Congress approved an additional $414 million for Alzheimer's research, bringing the total funding to $1.828 billion.[10] For FY 2019, Congress

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[3] National Institute on Aging, National Institutes of Health, *History*, U.S. Department of Health and Human Services, *available at* https://www.nia.nih.gov/about/history.
[4] *Id.*
[5] *Id.*
[6] The six objectives are: 1) create and maintain a plan to overcome AD/ADRD; 2) coordinate AD/ADRD research across federal agencies; 3) accelerate the development of treatment; 4) improve early diagnosis; 5) decrease racial and ethnic disparities; and 6) coordinate international bodies. National Alzheimer's Project Act, Public Law No: 111-375 (Jan. 4, 2011), *available at* https://www.congress.gov/bill/111th-congress/senate-bill/3036.
[7] The five goals consisted of: 1) prevent and effectively treat AD/ADRD by 2025; 2) optimize care, quality, and efficiency; 3) expand support for people with AD/ADRD and their families; 4) enhance public awareness and engagement; and 5) track progress and drive improvement. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, National Plan to Address Alzheimer's Disease (Dec. 3, 2018), *available at* https://aspe.hhs.gov/national-plans-address-alzheimers-disease.
[8] Consolidated and Further Continuing Appropriations Act, 2015, Public Law No. 113-235 (Dec. 16, 2014), *available at* https://www.congress.gov/113/plaws/publ235/PLAW-113publ235.pdf.
[9] BOLD Infrastructure for Alzheimer's Act, Public Law No: 115-406 (Dec. 31, 2018), *available at* https://www.congress.gov/bill/115th-congress/senate-bill/2076.
[10] Congressional Record (Mar. 22, 2018), vol. 164, no.50—Book III, H2701.

directed NIH to reserve $2.34 billion, an increase of $425 million from FY 2018.[11] Despite legislative action by Congress and increases in research funding, a cure or effective treatment for AD/ADRD remains out of reach.

There are promising developments, however. On October 22, 2019, Biogen announced that it planned to move forward in seeking regulatory approval from the U.S. Food and Drug Administration (FDA) of an investigational treatment for early Alzheimer's disease called aducanumab.[12] If approved by the FDA, this drug "would become the first therapy to reduce the clinical decline of Alzheimer's disease."[13] While promising, the drug has not been approved by the FDA to date; moreover, according to experts, an effective treatment for AD/ADRD will likely include several therapies.[14] Additionally, a recent paper published by researchers notes that a rare genetic mutation may have helped to delay Alzheimer's disease for a woman who was at risk for early onset of Alzheimer's disease.[15] This finding shifts the focus from the amyloid protein to the tau protein, and could inform and lead to new approaches to the treatment of Alzheimer's disease. These are just two examples of potential breakthroughs in the search for treatments and a cure for Alzheimer's disease, but additional research is needed.

Finding a cure or effective treatment for AD/ADRD will continue to require an all-hands-on-deck approach. Given NIA's substantial involvement in Alzheimer's Disease research, NIA plays an integral role in that approach. We request that written answers to the following questions be provided by January 30, 2020. We request you also provide a briefing to staff.

1. In what manner does NIA use past research results to determine which grant applicants will receive funding?

2. How does NIA/NIH evaluate AD/ADRD research results to create new grant announcements and awards to fund research that will build upon research results?

3. How does NIA determine which categories of AD/ADRD research will receive the most funding? Does NIA have a strategic plan for research funding allocation?

    a. If so, how often is the plan revised and what criteria is used to create the plan?

4. In fiscal years 2017-2019, what percent of grants and financial awards were distributed by NIA/NIH for AD/ADRD research awards for research that built upon AD/ADRD

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[11] H. Rept. 115-952, p. 529.
[12] Biogen, Biogen Plans Regulatory Filing for Aducanumab in Alzheimer's Disease Based on New Analysis of Larger Dataset from Phase 3 Studies (Oct. 22, 2019), *available at* http://investors.biogen.com/news-releases/news-release-details/biogen-plans-regulatory-filing-aducanumab-alzheimers-disease.
[13] *Id.*
[14] Tara Bahrampour, *In surprise turnaround, new analysis finds an Alzheimer's treatment may work*, WASH. POST (Oct. 22, 2019), *available at* https://www.washingtonpost.com/local/social-issues/in-surprise-turnaround-new-analysis-finds-an-alzheimers-treatment-may-work/2019/10/22/cb274fd8-f4e6-11e9-ad8b-85e2aa00b5ce_story.html.
[15] Linda Carroll, *Rare genetic finding may help in search for Alzheimer's therapies,* REUTERS (Nov. 4, 2019), *available at* https://www.reuters.com/article/us-health-alzheimers-genetics-idUSKBN1XE216.

research results already achieved and what percent funded new research? What are the correlating dollar amounts with each of those categories of financial awards?

5. In fiscal years 2017-2019, what were the dollar amounts of financial awards available for AD/ADRD research provided by all federal agencies other than NIA/NIH?

    a. Which federal agencies provided those awards and for what amounts?

6. How does NIA/NIH coordinate all research efforts funded by the federal government into focused results to achieve the primary goal of NAPA of effectively treating and preventing AD/ADRD by 2025?

    a. How does NIA/NIH determine which AD/ADRD awards will be grants and which will be cooperative agreements?

7. In what time-frame are NIA/NIH-funded research results shared with other federal agencies who are also conducting AD/ADRD research, such as the ASPE and CDC?

    a. How does NIA/NIH engage in communication and information exchange when sharing research results with the other federal agencies?

8. When research results produce failed responses to drugs as demonstrated in beta-amyloid related research,[16] what is the role of NIA in advising scientists to explore alternatives for future research funding investments?

    a. To what extent has NIA reviewed the beta-amyloid studies? Does NIA plan to allocate more grant money to less conventional AD/ADRD research, or research that does not focus on Tau or Beta-amyloid, than it has in past years? Why or why not?

9. What factors are weighed when NIA reviews grant applications? Does NIA consider the prior year's research results when deciding which grant applicants should receive funding? If so, how much weight is given to these considerations?

10. What has NIA research revealed about the various socioeconomic, ethnic, and racial groups disparities present in AD/ADRD?

    a. Has NIA funded research made any progress with respect to why racial disparities are present in AD/ADRD?

    b. Will the research results regarding disparities in AD/ADRD impact achieving the NAPA goal of effectively treating and preventing AD/ADRD by 2025?

[16] United States National Library of Medicine, National Institutes of Health, *Why do Trials for Alzheimer's Disease Drugs Keep Failing? A Discontinued Drug Perspective for 2010-2015, available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5576861/.

i. If so, how will that goal be impacted by those results?

ii. If so, what recommendations does NIA/NIH have to overcome any new obstacles that may be signaled by disparities in AD/ADRD?

Thank you for your attention to this request. Should you have any questions, and to schedule the requested briefing, please contact Brittany Havens or Diane Cutler of the Republican Committee Staff at (202) 225-3641.

Sincerely,

Greg Walden
Republican Leader

Brett Guthrie
Republican Leader
Subcommittee on Oversight
and Investigations

Michael C. Burgess, M.D.
Republican Leader
Subcommittee on Health